APR 2 0 2012

K113778

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Trade Name: Excelsior® XT-27™ Microcatheter

Generic Name: Percutaneous Catheter, Microcatheter

Classification: CLASS II, 21 CFR 870.1250

Submitted By: Stryker Neurovascular
47900 Bayside Parkway
Fremont, CA 94538-6515

Contact: Yoko Y Enrile

Predicate Device: K000177, Renegade™ Hi-Flo™ Microcatheter

K042568, Excelsior® SL-10 Pre-Shaped Microcatheter

Indications for Use: The Excelsior XT-27 Microcatheter is intended to assist in the delivery of diagnostic agents (such as contrast media), therapeutic agents, and non-liquid interventional devices (such as stents) that are indicated for use in the neurovasculature and with a catheter of 0.027 inches in inner diameter.

Device Description: The Excelsior® XT-27™ Microcatheter is a sterile, single lumen 0.027 in ID device with one tip marker designed to aid the physician in accessing distal vasculature when used with a guide catheter and steerable guidewire. Graded shaft stiffness ranging from a highly flexible tip to a semi-rigid proximal section aids the physician in tracking over selectively placed guidewires. A luer fitting located on the microcatheter hub is used for the attachment of accessories. One radiopaque tip marker is positioned at the distal tip of the device to facilitate fluoroscopic visualization. The Excelsior XT-27 Microcatheter is coated on the outer surface with Hydrolene™ coating which reduces friction during manipulation in the vessel.

The Excelsior XT-27 Microcatheters are available in effective lengths of both 135cm (53.1 inch) and 150 cm (59.1 inch), with two distal shaft configurations achieved through distal shaft lengths of 6 cm (XT-27 model) and 18 cm (XT-27 Flex model). Both straight tip and Pre-Shaped versions are available.

Accessories: Each Excelsior XT-27 Microcatheter is provided with accessories (a shaping mandrel, and peel away introducer) within a separate inner Tyvek™ pouch (Accessory pouch). The Excelsior XT-27 Microcatheter is available in a single pack (one unit per package) only. The device pouch and Directions for Use (DFU) are both provided inside a shelf carton.

Summary Differences in Technological Characteristics:

The Excelsior XT-27 Microcatheters introduce several enhanced design features:

a) The OD profile of the Excelsior XT-27 Microcatheter is smaller than the Renegade Hi-Flo Microcatheter.
b) The Excelsior XT-27 Microcatheter has up to five zones of polymer stiffness which vary from the distal to proximal shaft and help to enhance the trackability and pushability of the catheter.
c) The Excelsior XT-27 Microcatheter has a more supportive double helix winding reinforcement compared to the Renegade Hi-Flo Microcatheter.

Bench Test Summary:

Test	**Result**
Visual Inspection: Durable Hydrophilic Coating Surface Defects Surface-Extraneous matter	Met same criteria as predicate
Dimensional Measurement: Kink Radius of Curvature / Proximal Shaft Kink Distal OD Reduction Tip Configuration Catheter Hub	Met same criteria as predicate
Corrosion Resistance	Met same criteria as predicate

Simulated use: * Introduction * Tracking * Reposition / Deployment * Detachment * Overall Performance	Met same criteria as predicate
Advancement / Retraction Force	Met same criteria as predicate
In-vitro Cytotoxicity, MEM Elution Intracutaneous reactivity Acute systemic toxicity, Injection Sensitization, Guinea Pig Maximization Hemocompatibility, Direct Contact; Complement Activation C3a and SC5b-9; PTT; blood cell counts and hemoglobin / hematocrit levels Materials Mediated Pyrogen levels, Rabbit test USP impurities, <661> Latex test, ELISA Inhibition	Non-cytotoxic Non-irritating Non-toxic Non- sensitizing Non-hemolytic Non-pyrogenic None None

Predicate / Subject Device Comparison: Product Feature Comparison for Excelsior® SL-10 Pre-Shaped Microcatheter (K042568) and Renegade™ Hi-Flo™ Microcatheter (K000177)

Feature	K042568 Excelsior® SL-10 Pre-Shaped Microcatheter	K000177 Renegade™ Hi-Flo™ Microcatheter	Subject Device
Materials	PTFE, Pebax, Stainless Steel wire, Nylon, Santoprene	PTFE, Pebax, Vectran Fiber and Pt/Ir wire, Nylon, Santoprene	PTFE, Pebax, Stainless Steel wire, Nylon, Santoprene
Tip shape	Preshaped	Straight	Offers both shapes (Straight and Preshaped)
	Option of steam shaping by physician for proper adjustment to the anatomy prior to use	Option of steam shaping by physician for proper adjustment to the anatomy prior to use	Option of steam shaping by physician for proper adjustment to the anatomy prior to use
Effective Lengths	150 cm	135 cm, 150 cm	135 cm, 150 cm
Proximal /Distal OD	Proximal OD 2.4F Distal OD 1.7F	Proximal OD 3F Distal OD 2.8F	Proximal OD: 2.9F Distal OD: 2.7F
ID	0.0165 inch	0.027inch	0.027inch
Hydrophilic Coating Length	100 cm	60 cm	80 cm
Tip Length	6cm	10cm and 20cm	6cm and 18cm
Tip Markers	90%Pt-10%Ir	90%Pt-10%Ir	90%Pt-10%Ir
Coating	Polyvinylpyrrolidone Polyacrylamide	Hydropass Hydrophilic Coating	Polyvinylpyrrolidone Polyacrylamide
Method of supply	Sterile, single-use, non-pyrogenic	Sterile, single-use, non-pyrogenic	Sterile, single-use, non-pyrogenic

Summary of Substantial Equivalence: The Excelsior XT-27 Microcatheter subject of this submission is substantially equivalent to the predicate devices with regard to design, materials, sterilization, principle of operation, performance, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Stryker Neurovascular
c/o Ms. Tina Lochner
DEKRA Certification, Inc.
4377 County Line Road
Chalfont, PA 18914

APR 20 2012

Re: K113778
Trade/Device Name: Excelsior XT-27 Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, KRA
Dated: March 16, 2012
Received: March 22, 2012

Dear Ms. Lochner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113778

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Quynh Hoang

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K113778